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EXAMINER
BRUSCA, J

ART UNIT	PAPER NUMBER
1636	3

DATE MAILED: 01/19/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Pildguy

# Office Action Summary

Application No.  
09/182,102

Applicant(s)  
Haaf et al.

Examiner  
John S. Brusca

Group Art Unit  
1636



☐ Responsive to communication(s) filed on \_\_\_\_\_

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 18-21 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 18-21 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☒ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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## DETAILED ACTION

### *Drawings*

1. This application has been filed with informal drawings which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed.

### *Specification*

2. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

3. The disclosure is objected to because of the following informalities:

The disclosure is replete with grammatical and typographical errors, for example at page 51, lines 15-16. The Applicants are requested to carefully review the specification for errors and make appropriate amendments in response to this Office Action. If extensive amendments are required to the specification, a substitute specification that does not include the claims should be filed.

The specification lists a reference by Haaf, T (1995) on page 58 that could not be located in literature databases. If the reference does not exist, the citation should be corrected or deleted on page 58 and as cited in the specification.

Appropriate correction is required.

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*Claim Rejections - 35 USC § 112*

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 21 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

In *In re Wands* (8 USPQ2d 1400 (CAFC 1988)) the CAFC considered the issue of enablement in molecular biology. The CAFC summarized eight factors to be considered in a determination of "undue experimentation". These factors include: (a) the quantity of experimentation necessary; (b) the amount of direction or guidance presented; (c) the presence or absence of working examples; (d) the nature of the invention; (e) the state of the prior art; (f) the relative skill of those in the art; (g) the predictability of the art; and (h) the breadth of the claims.

In considering the factors for the instant claims:

a) In order to practice the claimed invention one of skill in the art must identify a Rad51 mutation that is associated with a disease. For the reasons discussed below, there would be an unpredictable amount of experimentation required to use the claimed invention.

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b) The specification states on page 16 that a preferred embodiment of the disclosed method of identifying mutant Rad51 genes is to identify a mutant gene that is associated with a disease. No further guidance is presented in the specification to identify a mutant Rad51 gene that is associated with a disease.

c) The specification does not present a working example of identifying a mutant Rad51 gene that is associated with a disease.

d) The invention is drawn to a method of identifying a Rad51 mutation that is associated with a disease

e) Vispe et al. was published before the filing date of the immediate parent Application No. 09/007020, and was received in the STIC library on 3/5/98. Vispe et al. reviews the prior art concerning Rad51, and states that Rad51 is known to bind p53, BRCA1, and BRCA2 proteins. Vispe et al. does not show a disease caused by a mutation of Rad51. Vispe et al. states in the conclusion on page 590:

“Considering the role of Rad51 in recombination and potentially in cell proliferation, and its association with both BRCA1 and BRCA2, it is possible that mutations in either gene could increase genomic instability and/or disturb the cell cycle, leading to tumorigenesis. To support this hypothesis it would be interesting to look for RAD51 mutations in tumor cells.”

Therefore, Vispe merely suggests that a screen to determine the possible existence of Rad51 mutations might be useful to study tumorigenesis.

f) The skill of those in the art of molecular biology is high.

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g) The prior art does not predict that Rad51 mutations exist or that Rad51 mutations cause disease.

h) The claims are broad in that they are drawn to a method of identifying Rad51 mutations that are associated with disease although there is no guidance in the specification or the prior art as to what mutations of Rad51 meet the claimed limitations.

The skilled practitioner would first turn to the specification for guidance in performing the claimed method of identifying Rad51 mutations associated with disease. However, the specification does not disclose mutations of Rad51 that meet the claimed limitations, and so said practitioner would not be able to determine success or failure of the method. As such, the skilled practitioner would turn to the prior art for such guidance. However, the prior art does not teach the claimed method or Rad51 mutations that are associated with disease. Finally, said practitioner would turn to trial and error experimentation to perform the claimed method without guidance from the specification or the prior art. Such represents undue experimentation.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 18-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claims 18-19 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted step is comparing the sequence of said Rad51 gene to a known Rad51 gene. The rejection would be overcome by adding the missing step.

Claim 18 recites the limitation "the endogenous Rad51 genes". There is insufficient antecedent basis for this limitation in the claim. The rejection would be overcome by amending claim 18 to recite "an endogenous Rad51 gene of a cell".

Claims 18-21 are indefinite because the preamble recites a method of identifying a mutant Rad51 gene while the steps merely consist of comparing two Rad51 genes. The rejection would be overcome by amending the preamble of claim 18 to recite "A method of determining whether a cell contains a mutant Rad51 gene."

For the purpose of examination, the claims have been assumed to incorporate the suggested amendments.

### ***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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7. Claims 18-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Ogawa et al. The claims are drawn to a method of comparing Rad51 gene sequences for differences. Ogawa et al. shows in figures 7 and 8 a comparison of Rad51 protein sequences determined by a comparison of Rad51 gene sequences. Ogawa et al. shows in figures 7 and 8 numerous differences between the compared Rad51 genes.

Therefore, Ogawa et al. anticipates the claimed invention.

### *Conclusion*

8. Certain papers related to this application may be submitted to Art Unit 1636 by facsimile transmission. For routine submissions the FAX number is (703) 308-4242. For FAX transmissions in cases in which the Examiner has been notified by phone to expect the transmission, the FAX number is (703) 305-7939. In such cases please call the Examiner at (703) 308-4231 at the time of transmission to expedite delivery of the fax. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6 (d)). NOTE: If applicant *does* submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office.

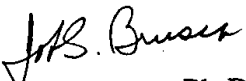
Any inquiry concerning this communication or earlier communications from the examiner should be directed to John S. Brusca, Ph.D. whose telephone number is (703) 308-



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4231. The examiner can normally be reached on Monday through Friday from 9 AM to 5 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, George Elliott, Ph.D., can be reached at (703) 308-4003.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

  
John S. Brusca, Ph.D.

Examiner